

Serial No. 10/748,003
Response to Office Action

Remarks

Claims 1-11 are pending. Applicants have amended claims 1, 2, 9 and 10. Applicants address each of the rejections imposed in the Office Action of December 30, 2005.

Claim Rejections - 35 USC §103

Claims 1-5, 7-11 over Mathiowitz et al. (US 2001/0043914, 2001) and Mathiowitz et al. (U.S. Patent No. 6,235,313, 2001)

Applicants request the Examiner to reconsider the rejection for the following reasons. Applicants have amended the claims to recite a method in which polymeric microspheres which encapsulate sulindac and IL-12 (either in the same microspheres or different microspheres) are administered orally and that the two agents have a synergistic effect on inhibition of tumor growth. Support for administration of sulindac and IL-12 in the same or different microspheres is present on page 8, lines 22-29. Further, a synergistic effect of administration of sulindac and IL-12 is demonstrated in animal studies and presented in Example 11. Applicants respectfully point out that neither of the cited references of Mathiowitz teach or even suggest the administration of IL-12 and sulindac to obtain a synergistic inhibitory effect. Therefore, Applicants assert that claim 1 as amended herein and its dependent claims are not obvious over the cited references.

Claims 1-3, 5,6 and 8 over Giardiello et al. (1996) in view of Mathiowitz (U.S. Patent No. 6,235,313, 2001)

Applicants request the Examiner to reconsider the rejection for the following reasons. As discussed above, Applicants have amended claim 1. It is respectfully submitted that while Giardiello et al. may describe administration of sulindac, neither reference, teaches or even suggests administration of sulindac and IL-12 to achieve a synergistic inhibitory effect on the growth of tumors. Therefore, Applicants assert that the claim 1 as amended herein and its dependent claims are not obvious over the cited references.

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Claim 4 over Giardiello et al. (1996) in view of Mathiowitz (U.S. Patent No. 6,235,313, 2001 and further in view of Egilmez et al. (2000)

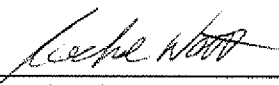
Applicants request the Examiner to reconsider the rejection for the following reasons. As discussed above, Applicants have amended claim 1, which claim 4 depends upon. As discussed above, the cited references of Giardiello et al., Mathiowitz et al., or Egilmez et al. do not teach or suggest the administration of sulindac and IL-12 to obtain a synergistic tumor inhibitory effect as described and claimed herein. Because claim 4 describes a phase inversion method for the preparation of microspheres used in the method of claim 1, and because Applicants assert claim 1 is patentable, it follows that claim 4 is also patentable over the cited references.

Conclusion

Based on the above arguments and amendments, Applicants respectfully submit that none of the cited references, either alone or in combination render the present claims obvious. Applicants assert claim 1, is allowable, and therefore, dependent claims 2-11 are also allowable. Therefore, Applicants respectfully request the Examiner to allow these claims.

This response is being filed within three months of the Office Action and therefore it is believed no fee is due. However, if any fee is due, the Examiner is authorized to charge that to Deposit Account No. 08-2442.

Respectfully submitted,
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